DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 103 and 248

Powers and Duties of Service Officers: Availability of Service Records, Change of Nonimmigrant Classification; Denial of Appeal

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: This is a proposal to change the regulation concerning the alien's right to appeal the denial of an application for change of nonimmigrant status by removing that right. In the case of denial, an alien has the opportunity to file a motion to reopen or reconsider, and a separate right to appeal merely creates delays in adjudicating the application.

DATE: Comments must be received on or before August 30, 1982.

ADDRESS: Please submit written comments in duplicate to the Commissioner of Immigration and Naturalization, Room 7100, 425 Eye Street, NW., Washington, DC 20536.

FOR FURTHER INFORMATION CONTACT:

For General Information: Stanley J. Kieszkiel, Acting Instructions Officer, Immigration and Naturalization Service, 425 Eye Street, NW., Washington, D.C. 20536, telephone: (202) 633–3048.

For Specific Information: Teresa J. De Silva, Immigration Examiner, Immigration and Naturalization Service, 425 Eye Street, NW., Washington, D.C. 20536, telephone: (202) 633–3946.

SUPPLEMENTARY INFORMATION: This rule proposes to amend §§ 103.1(m)(15) and 248.3(d) of Title 8 to remove the right to appeal the denial of an application for change of nonimmigrant status. The majority of applications under section 248 of the Act are factual and easily disposed of. In many instances they are no more complex than an application for extension of stay which is not appealable. Service experience has shown that a large number of aliens who were admitted as B–2 visitors for pleasure use the Form I–506 application as a means of continuing their stay in the U.S., as evidenced by B–2 aliens applying for change of nonimmigrant status after their applications for extension of stay have been denied. A large proportion of these applications are frivolus and submitted merely in an attempt to prolong the alien's stay in the United States. The appeal provides a means for the nonimmigrant alien to gain that time which can no longer be obtained under section 214 (of the Act) procedure. Regional statistics support this fact, as an average 92% of section 248 appeals are dismissed by the Regional Commissioners.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

This rule will not be a major rule within the meaning of section (b) of E.O. 12291.

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Authority delegation, Organization and functions.

8 CFR Part 248

Administrative practice and procedure, Aliens.

Accordingly, Title 8 of the Code of Federal Regulations is proposed to be amended as follows:

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS: AVAILABILITY OF SERVICE RECORDS

§ 103.1 [Amended]

1. In § 103.1, paragraph (m)(15) is removed and paragraphs (m)(16) through (m)(22) are renumbered (m)(15) through (m)(21).

(Sec. 103, 248 of the Immigration and Nationality Act as amended; 8 U.S.C. 1103, 1258)

PART 248—CHANGE OF NONIMMIGRANT CLASSIFICATION

1. In § 248.3, paragraph (d) is revised to read as follows:

§ 248.3 Application.

* * * * *

(d) *Denial of application.* When the application is denied the applicant shall be notified of the decision and the reasons for the denial. There is no appeal from the denial of the application under this chapter.

(Sec. 103, 248 of the Immigration and Nationality Act as amended; 8 U.S.C. 1103, 1258)

Dated: July 20, 1982.

Alan C. Nelson,

Commissioner of Immigration and Naturalization.

[FR Doc. 82–20718 Filed 7–29–82; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 354

[Docket No. 80N–0228]

Drug Products for the Relief of Oral Discomfort for Over-the-Counter Human use; Advance Notice of Proposed Rulemaking; Extension of Time for Comments and Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 22, 1982, the comment period and to November 22, 1982, the reply comment period for the advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) drug products for the relief of oral discomfort. This action is being taken in response to a request to allow more time for interested persons to address adequately several important issues raised by the Panel and to consult experts so that more informed comments may be submitted to FDA.

DATES: Written comments by October 22, 1982, and reply comments by November 22, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 1982 (47 FR 22712), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of drug products for the relief of oral discomfort for OTC human use. This advance notice of proposed rulemaking, which was based on the recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until August 23, 1982, to comment on the advance notice of proposed rulemaking and until September 22, 1982, for reply comments.

In response to the proposal, The Proprietary Association requested a 60-day extension of the comment period in order to allow adequate time for the association to address several important issues raised by the Panel, including the Panel's combination drug policy and its definition of toothache. The Association stated that it plans to contact experts on these issues in the course of its preparation of comments on the proposal. The Association pointed out the difficulty of contacting such experts during the summer months.

FDA has carefully considered the request. The agency believes that information described in the request may be of assistance in establishing the safety and effectiveness of OTC drug products for the relief of oral discomfort and is in the public interest. The agency considers a general extension of the comment period for 60 days to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to October 22, 1982, and the reply comment period is extended to November 22, 1982. Comments may be seen in the Dockets Management Branch, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-20475 Filed 7-29-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 356

[Docket No. 81N-0033]

Oral Health Care Drug Products for Over-the-Counter Human Use; Advance Notice of Proposed Rulemaking; Extension of Time for Comments and Reply Comments

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 22, 1982, the comment period and to December 22, 1982 the reply comment period for the advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) oral health care drug products. This action is being taken in response to two requests to allow more time for interested persons to address adequately several important issues raised by the Panel and to consult experts so that more informed comments may be submitted to FDA.

DATES: Written comments by November 22, 1982, and reply comments by December 22, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 25, 1982 (47 FR 22760), FDA issued an advance notice of proposed rulemaking to establish conditions for the safety, effectiveness, and labeling of oral health care products for OTC human use. This advance notice of proposed rulemaking, which was based on the recommendations of the Advisory Review Panel on OTC Oral Cavity Drug Products, is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until August 23, 1982, to comment on the advance notice of proposed rulemaking and until September 22, 1982, for reply comments.

In response to the proposal, The Proprietary Association requested a 60-day extension of the comment period in order to allow adequate time for the association to address important issues raised by the Panel concerning antimicrobial agents and OTC mouthwash products. The Association stated that it plans to solicit the views of dental researchers and scientists who did not participate in the Panel's deliberations so that FDA may have the widest possible views regarding the Panel's recommendations. Warner-Lambert Co. requested a 90-day extension to permit careful and thorough evaluation of the Panel's report and to consult other oral health care experts in order to respond with meaningful comments. The company pointed out the difficulty of contacting such experts during the summer months.

FDA has carefully considered the requests. The agency believes that information described in the requests may be of assistance in establishing the safety and effectiveness of OTC oral health care drug products and is in the public interest. Because of the length of the Panel's report, the agency considers a general extension of the comment period for 90 days to be appropriate. Accordingly, the comment period for submissions by any interested person is extended to November 22, 1982, and the reply comment period is extend to December 22, 1982. Comments may be seen in the Dockets Management Branch, Food and Drug Administration, at the address noted above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-20476 Filed 7-29-82; 8:45 am]

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21 CFR Part 600

[Docket No. 82N-0138]

Biological Products; Inspection Frequency of All Licensed Biological Establishments and Their Additional Location(s)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by changing the required minimum frequency of inspections for all licensed biological establishments and their additional location(s) from at least once every year to at least once every 2 years. This action is being proposed (1) to provide flexibility for the agency to reduce the inspection burden on a specific portion of the regulated drug and device industry; (2) to provide the agency with greater flexibility in management of its resources; and (3) to provide a uniform requirement for frequency of inspection for all drugs and devices consistent with requirements in the Federal Food, Drug, and Cosmetic Act.

DATE: Comments by September 28, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rada Proehl, National Center for Drugs and Biologics (HFB-620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: Since Congressional approval of the Biologics Control Act in 1902, biological products entering into interstate commerce have been required to be licensed under Federal law. In 1903, the Secretary of the Treasury approved the first regulations for the enforcement of the Biologics Control Act. The regulations, promulgated by a board consisting of the Surgeon General of the Public